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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,517	12/27/2001	Pu Zhou	12013/61601	9382

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EXAMINER
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SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/026,517	<b>Applicant(s)</b> ZHOU, PU	
	<b>Examiner</b> Laura C. Schell	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9,11-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 13-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,12 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "206" and "26" have both been used to designate entrance orifice in paragraph [19] and in Fig. 2. Furthermore, reference characters "46" and "35" have both been used to designate flushing orifices in paragraph [29] and Fig. 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: Paragraphs 20 and 22 of the specification disclose that the hardness of the sections decreases, then increases and then decreases again. However, when the given durometer hardnesses were applied to their respective section in Fig. 2, from sections 23 to 27 the hardness decrease (between 23 and 24), then increase (between 24 and 25) and then increase again (between 25 and 27) which is therefore quite opposite from what the

specification and the claims disclose as the patentable subject matter. An explanation accompanying a correction is required to argue that the correction is not an introduction of new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US Patent No. 6,524,303) in view of Fleming, III (US Patent No. 5,718,678). Garibaldi discloses a medical catheter system comprising: a first catheter (Fig. 1) having an entrance orifice (24), an exit orifice (26), a channel connecting the entrance and the exit orifice, a wall (22) surrounding the channel, the hardness of the wall surrounding the channel, when considered from an initial reference point at the entrance orifice and traveling towards the exit orifice, regardless of the orientation of the wall, decreasing in hardness in a first distinct region then increasing in hardness in a second distinct region and then decreasing in hardness again in a third distinct region, the hardness of the third region being different than the hardness of the first region. Garibaldi discloses in col. 3, lines 46-55 that the catheter increases in flexibility from 24 to 26, which is equivalent to the catheter decreasing in hardness from 24 to 26. Garibaldi further discloses in this paragraph that between the sections of decreasing

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hardness, a region of increased stiffness can be provided, thus creating the distinct pattern of decreasing hardness, increasing hardness and then decreasing hardness. Garibaldi, however, does not disclose a second and third catheter within the first catheter. Fleming, discloses a second catheter (Fig. 4, 26) which is sized to move within the first catheter (42) as well as a third catheter (12) which moves within the second catheter. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Garibaldi with the nested catheters as taught by Fleming, in order to provide a multiply flexible catheter with several other catheters within it to deploy for various procedures.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi in view of Fleming and further in view of Lafontaine (US Patent No. 5,662,621).

Garibaldi in view of Fleming discloses the device substantially as claimed except for the second catheter having flushing orifices. Lafontaine, however, discloses a first catheter (Fig. 5, 26) with a second catheter within it (42) wherein the second catheter has flushing orifices (126). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Garibaldi in view of Fleming with the idea of using a second catheter with flushing orifices within a first catheter, as taught by Lafontaine, in order to provide a way of using a first catheter to guide the second catheter within it to a spot and using the second catheter for flushing within the first catheter.

Claims 9, 11, 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinoshita et al. (US Patent No. 6,280,434) in view of Noone et al. (US Patent No. 6,591,472). Kinoshita discloses a medical catheter system comprising: a first steerable guide catheter (Fig. 1, 1) having an entrance orifice (near 7), an exit orifice (3), and a first wall surrounding a channel linking the entrance orifice and the exit orifice (see Fig. 8), the first wall having a bendable curve memory portion (col. 3, line 35), wherein the bendable curve memory portion is bent into a predetermined shape (Figs. 1-5 show the catheter bent into shape with a bend between 1 and 4, and a curved part at 2; see also col. 1, lines 30-34). Kinoshita, however, does not disclose that the first wall contains three layers. Noone, however, discloses a catheter (Fig. 1) with a first wall (15) wherein the first wall contains three different layers (Fig. 19; layers include 70, 100 and 115; also see col. 15, line 66 through col. 16, line 29). Noone further discloses that each layer has a different hardness. Layer 70 is a hard metal wire (col. 8, lines 49-60), layer 100 is a layer of a first durometer hardness (col. 16, lines 15-23 wherein the "initial layer segment" is designated in col. 18 as element 100) and layer 115 is of a second durometer hardness (col. 16, lines 23-26). Noone further discloses that layer 70 is comprises of shape memory wire, and therefore would produce a shape memory catheter (col. 8, line 56). Noone also discloses that the inside surface of the first catheter comprises a lubricious layer (65; see col. 8, lines 33-36). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Kinoshita with the layered wall structure of Noone, as a layered wall structure

is well known in the art and is used to provide catheters with customized patterns of rigidity.

***Allowable Subject Matter***

Claims 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's arguments with respect to claims 1, 3-9, 11, 12 and 29 have been considered but are moot in view of the new ground(s) of rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

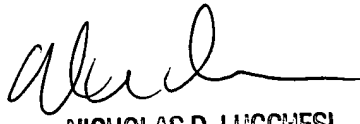
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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